INITIAL STATEMENT OF REASONS

Note that this is the second 45-day public notice and **bold font** indicates there was a modification to that section from the original 45-day public notice dated June 10, 2016. The CDSS initially noticed these regulations to the public for a 45-day comment period in the Office of Administrative Law California Regulatory Notice Register, Register 2016, No. 24-Z, dated June 10, 2016. These regulations were considered as Item #1 at a public hearing held on July 27, 2016, in Sacramento, California.

a) Specific Purpose of the Regulations and Factual Basis for Determination that Regulations Are Necessary

Section 87101(d)(2)

Specific Purpose:

This section adds a definition for the term "deep tissue pressure injury" to the regulations.

Factual Basis:

This section adds a definition for "deep tissue pressure injury" and is necessary to provide clarity to assist a licensee in understanding a potentially unfamiliar term that appears in regulations. The definition for "deep tissue pressure injury" is consistent with terminology used by the National Pressure Ulcer Advisory Panel (NPUAP) in an April 13, 2016 NPUAP Press release (http://www.npuap.org/national-pressure-ulcer-advisory-panel-npuap-announces-a-change-in-terminology-from-pressure-ulcer-to-pressure-injury-and-updates-the-stages-of-pressure-injury/).

A "deep tissue pressure injury" is defined by the NPUAP as "Intact or non-intact skin with localized area of persistent non-blanchable deep red, maroon, purple discoloration or epidermal separation revealing a dark wound bed or blood filled blister. Pain and temperature change often precede skin color changes. Discoloration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly to reveal the actual extent of tissue injury, or may resolve without tissue loss. If necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle or other underlying structures are visible, this indicates a full thickness pressure injury (Unstageable, Stage 3 or Stage 4)..."

The California Department of Social Services (CDSS) is using its broad authority to promulgate regulations for licensed Residential Care Facilities for the Elderly (RCFEs) in Health and Safety Code section 1569.30 to clarify the definition for greater ease of understanding by licensees. The definition addresses the appearance, cause and staging of deep tissue pressure injuries. It also clarifies what "epidermis" and "shear," referred to in the NPUAP definition, are. The term "epidermis" is described as the "protective outer layer

of the skin." The term "shear" is described as "an action or stress that causes internal parts of the body to become deformed," consistent with information about shear in "Shear: A contributory factor in pressure ulceration" (http://www.npuap.org/wp-content/uploads/2012/02/Shear_slides.pdf).

Sections 87101(d)(3) through (d)(11) are Renumbered from Sections 87101(d)(2) through (d)(10)

Specific Purpose/Factual Basis:

Sections 87101(d)(2) through (d)(10) are renumbered to Sections 87101(d)(3) through (d)(11) due to adopting Section 87101(d)(2) above.

Section 87101(h)(1)

Specific Purpose:

This section is amended to replace the term "dermal ulcers" with the term "pressure injuries" in the definition for "healing wounds." It is also amended to remove "as diagnosed by a physician" and "that are being treated by an appropriate skilled professional." There are grammatical changes to the section to remove the comma after "physician" and revise "appropriate" to "appropriately."

Factual Basis:

Amendment to this section, which defines "healing wounds," to replace "dermal ulcers" with "pressure injuries" is necessary to clarify that Stage 1 and 2 "pressure injuries" are also considered to be "healing wounds." This amendment is consistent with a NPUAP change in terminology from "pressure ulcer" to "pressure injury" announced in the <u>April 13, 2016 NPUAP press release</u> (http://www.npuap.org/national-pressure-ulcer-advisory-panel-npuap-announces-a-change-in-terminology-from-pressure-ulcer-to-pressure-injury-and-updates-the-stages-of-pressure-injury/).

Also according to the press release, the NPUAP defines a Stage 1 pressure injury as having "intact skin with a localized area" of abnormality. A Stage 2 pressure injury is defined by the NPUAP as a "partial-thickness loss of skin with exposed dermis" in which the injury has a wound bed that may be pink or red in color and moist. The NPUAP further states that the injury may also look like "an intact or ruptured serum-filled blister."

The references to healing wounds being diagnosed by a physician and being treated by an appropriately skilled professional are being removed because it is inappropriate to include regulatory language in a definition. The requirements for diagnosis and treatment appear in regulations such as Section 87611, addressing general requirements for allowable health conditions, and Section 87631, addressing healing wounds.

Section 87101(p)(3)

Specific Purpose:

This section adds a definition for the term "pressure injury" to the regulations.

Factual Basis:

This section adds a definition for "pressure injury" and is necessary to provide clarity to assist a licensee in understanding a potentially unfamiliar term that appears in regulations. The definition for "pressure injury" is consistent with the NPUAP change in terminology from "pressure ulcer" to "pressure injury."

A "pressure injury" is defined by the NPUAP as "... localized damage to the skin and/or underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue." The NPUAP also defines Stage 1, 2, 3 and 4 pressure injuries.

The CDSS is using its broad authority to promulgate regulations for licensed RCFEs in Health and Safety Code section 1569.30 to clarify the definition for greater ease of understanding by licensees. The definition addresses the appearance, cause and staging of pressure injuries. It also clarifies what "shear," referred to in the NPUAP definition, is. The term "shear" is described as "an action or stress that causes internal parts of the body to become deformed," consistent with information about shear in "Shear: A contributory factor in pressure ulceration" (http://www.npuap.org/wp-content/uploads/2012/02/Shear_slides .pdf).

Sections 87101(p)(4) through (p)(6) are Renumbered from Sections 87101(p)(3) through (p)(5)

Specific Purpose/Factual Basis:

Sections 87101(p)(3) through (p)(5) are renumbered to Sections 87101(p)(4) through (p)(6) due to adopting Section 87101(p)(3) above.

Section 87101(u)(2)

Specific Purpose:

This section adds the word "Care" to the term "Unlicensed Residential Facility for the Elderly."

Factual Basis:

The addition of "Care" is necessary for consistency with the term "Residential Care Facility for the Elderly" as defined in Section 87101(r)(5) and as used in the California Code of Regulations, Title 22, Division 6, Chapter 8, Residential Care Facilities for the Elderly (RCFE).

Sections 87101(u)(2)(B)1. through (u)(2)(C)2. are Renumbered from Sections 87101(u)(2)(B)(1) through (u)(2)(C)(2)

Specific Purpose/Factual Basis:

Sections 87101(u)(2)(B)(1) through (u)(2)(C)(2) are renumbered to Sections 87101(u)(2)(B)1. through (u)(2)(C)2. to correct the formatting of items in the outline *from* numbers within parentheses that are redundant with previous outline numbers within parentheses *to* numbers without parentheses and followed by a period. No changes are being proposed to the regulation text.

Section 87101(u)(3)

Specific Purpose:

This section adds a definition for the term "unstageable pressure injury" to the regulations.

Factual Basis:

This section adds a definition for "unstageable pressure injury" and is necessary to provide clarity to assist a licensee in understanding a potentially unfamiliar term that appears in regulations. The definition for "unstageable pressure injury" is consistent with terminology used by the NPUAP in its <u>April 13, 2016 NPUAP press release</u> (http://www.npuap.org/national-pressure-ulcer-advisory-panel-npuap-announces-a-change-in-terminology-from-pressure-ulcer-to-pressure-injury-and-updates-the-stages-of-pressure-injury/).

An "unstageable pressure injury" is defined by the NPUAP as "Full-thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because it is obscured by slough or eschar. If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed. Stable eschar (i.e. dry, adherent, intact without erythema or fluctuance) on the heel or ischemic limb should not be softened or removed."

The CDSS is using its broad authority to promulgate regulations for licensed RCFEs in Health and Safety Code section 1569.30 to clarify the definition for greater ease of understanding by licensees. The definition addresses the appearance of unstageable pressure injuries. It also clarifies what "slough" and "eschar," referred to in the NPUAP definition, are. The terms "slough" and "eschar" refer to "abnormal tissue," consistent with the description of slough as being confused with normal anatomical tissues and eschar as

necrotic granulation tissue in "<u>Identifying Types of Tissues Found in Pressure Ulcers</u>" (http://www.woundsource.com/blog/identifying-types-tissues-found-pressure-ulcers).

<u>Section 87102</u>

Specific Purpose:

This section is amended to clarify which forms listed in this section apply only to RCFEs and which forms listed in this section also apply to other licensing categories. It is also amended to clarify that all of the specified listed forms are incorporated into regulations by reference in this section.

Factual Basis:

Amendments to this section are necessary for further clarity. They distinguish between the specified forms in the forms listed in this section that apply only to RCFE regulations and the specified forms in the forms listed in this section that apply to other community care facility (Group Homes and Adult Residential Facilities) regulations and to RCFE regulations. Forms that apply only to RCFE include such forms as the Core of Knowledge Training Standard (01/16) - RCFE 80-Hour Initial Certification, while forms that also apply to other community care facilities include such forms as the LIC 9139 (01/16) - Renewal of Continuing Education Course Approval, Administrator Certification Program.

Section 87102(1)

Specific Purpose:

This section is adopted to incorporate a new form, the Residential Care Facility for the Elderly (RCFE) Complaint Poster (PUB 475, 1/15), that only applies to RCFEs, by reference in these regulations.

Factual Basis:

Adoption of this section is necessary for consistency with statute in Health and Safety Code section 1569.33, amended in statute by Senate Bill (SB) 895 (Chapter 704, Statutes of 2014). This statute required the California Department of Social Services (CDSS) to design a poster or cause a poster to be designed that contains information on how to report complaints. The CDSS has made this poster available to licensees and requires that it, or a poster that is consistent with the content of the poster provided by CDSS, be posted in all RCFEs.

Section 87109(b)

Specific Purpose:

This section is amended to revise the requirement that licensees notify specified parties at least sixty (60) days before the effective date of any change in ownership of a RCFE to at least thirty (30) days prior to such a change.

Factual Basis:

Amendment of this section is necessary to clarify the timeframe for licensees to provide notification of change in ownership in regulation. It is also necessary for consistency with statute. Health and Safety Code section 1569.191(a)(1), amended in statute by Assembly Bill (AB) 878 (Chapter 526, Statutes of 1993), requires that licensees provide written notice to CDSS and residents or their legal representatives of the licensee's intent to sell a RCFE at least thirty (30) days prior to transfer of the property or business.

Modification:

Following the public hearing, the CDSS is making a change to this section for clarity purposes.

The CDSS is deleting the phrase "...the effective date that any change in ownership of the facility occurs as required by..." and adding the phrase "...any of the events specified in..." to clarify that the specified timeframe applies to any of the events, i.e., sale or transfer of the property or business or a bona fide offer is made that is expected to result in the pending sale or transfer of a facility, specified in Health and Safety Code section 1569.191(a)(1).

Section 87309(b)

Specific Purpose:

This section is amended to establish the requirement that medicines which are centrally stored must be stored as specified and update the reference to subsection (c) of Section 87465.

Factual Basis:

Amendment of this regulation is necessary to clarify that the storage requirement does not apply to all medications, only those that must be centrally stored as specified in the referenced regulations section. It is also necessary for consistency with regulations in the referenced Section 87465. The referenced regulations have requirements for medications which are centrally stored, including the circumstances under which medication must be centrally stored.

Amendment of this regulation to remove the incorrect reference to Section 87465(c) is necessary for consistency in referencing a related regulation. Section 87465(c) specifies requirements for licensees to assist residents with self-administration of medication, while Section 87465(h) specifies requirements for medications to be centrally stored, which is the subject of this regulation. Barclays, which provides access to the California Code of Regulations (CCR), Title 22, Division 6, RCFE through the Office of Administrative Law website, became aware of the incorrect reference as a result of complaints from the public. The incorrect reference also appears in the public CCR, Title 22, RCFE regulations, which are accessed through CDSS Community Care Licensing Division (CCLD) website. Since the subsection may change by renumbering in future regulations packages, CDSS is repealing and not replacing the incorrect reference, but is retaining the reference to Section 87465, which contains the correct regulation on central storage of medications.

<u>Section 87468(a)</u>

Specific Purpose:

This section is amended to 1) replace "Each resident" with "Residents in residential care facilities for the elderly" and 2) replace "the following:" with "those listed below."

Factual Basis:

This regulatory change is necessary to clarify that personal rights are provided to all residents in RCFEs as specified in Section 87468.

Section 87468(a)(1)

Specific Purpose:

This section is adopted to add "Residents in all facilities shall have the following rights."

Factual Basis:

This regulatory change is necessary to clarify that residents in all facilities continue to be afforded the personal rights in existing regulations. Addition of regulation is necessary to comply with Health and Safety Code sections 1569.265 and 1569.267, added by AB 2171 (Chapter 702, Statutes of 2014). These statutes establish personal rights for residents in privately operated RCFEs and specifies that these rights are to be honored in addition to those addressed by existing regulations. These changes to statute do not change the requirement that personal rights in existing regulations continue to apply to residents in publicly operated facilities.

The remainder of these regulations comprise existing personal rights in Section 87468 that have applied, and will continue to apply as amended, to both privately operated and publicly operated RCFEs.

Sections 87468(a)(1)(A) through (a)(1)(J) are Renumbered from Sections 87468(a)(1) through (a)(10)

Specific Purpose/Factual Basis:

Sections 87468(a)(1) through (a)(18) are renumbered to Sections 87468(a)(1)(A) through (a)(1)(R) to accommodate the adoption of Section 87468(a)(1) above.

Amendment of **Section 87468(a)(1)(A)** is necessary to replace the phrase "his or her" in existing regulatory language with the word "their" for clarity. The CDSS is using the gender-neutral reference "their" to apply personal rights equally to residents in RCFEs who may identify as male or female, as neither male or female, or as both male and female.

Section 87468(a)(1)(D) is being amended post-hearing to restore existing language to the personal right so that it reads: "To be informed by the licensee of the provisions of law regarding complaints and of procedures to confidentially register complaints, including, but not limited to, the address and telephone number of the complaint receiving unit of the licensing agency." It is also being amended post-hearing to remove "confidentially contact the Community Care Licensing Division of the California Department of Social Services, the long-term care ombudsman, or both, regarding grievances against the facility" and adopt the right "...to contact the agencies specified in Health and Safety Code section 1569.885."

This regulatory change is necessary to clarify that residents in RCFEs continue to have the right to be informed of law and procedures in regard to complaints. This regulation is also necessary to establish a personal right that complies with and references Health and Safety Code section 1569.885(c), added to statute by SB 211 (Chapter 409, Statutes of 2003). This statute requires that residents be informed of, and have, the right to contact specified agencies, which include the Community Care Licensing Division of the California Department of Social Services and the long-term care ombudsman, to make complaints in regard to a licensed facility. It is not necessary to repeat the content of statute in regulation since the requirement is clear in the statute, which is incorporated by reference in regulation.

Amendment of **Section 87468(a)(1)(E)** is necessary to replace the phrase "his or her" in existing regulatory language with the word "their," insert the phrase "either in or outside the facility," and remove the sentence "Attendance at religious services, either in or outside the facility, shall be on a completely voluntary basis." This regulatory change is necessary for clarity. The CDSS is using the gender-neutral reference to "their" to apply personal rights equally to residents in RCFEs who may identify as male or female, as neither male or female, or as both male and female. The second sentence of the regulation is unnecessary since attending religious services on a voluntary basis is the same as attending religious services of choice in the first sentence. Residents continue to be permitted to attend religious services or activities either in or outside the facility.

Amendment of Section 87468(a)(1)(F) is necessary to move the sentence "This does not prohibit the establishment of house rules, such as the locking of doors at night, for the

protection of residents; nor does it prohibit, with permission of the licensing agency, the barring of windows against intruders" to adopt **Subsection** (a)(\mathbf{l})(\mathbf{f})(1.) of this section. This regulatory change is necessary for clarity. It separates the conditions of not prohibiting house rules or other precautions that apply to the personal right from the personal right. The personal right is permitted to stand alone and be followed by the conditions that apply.

Amendments to **Sections 87468(a)(1)(G) through (a)(1)(I)** are necessary to replace the phrase "his or her" in existing regulatory language with the word "their." They are also being amended to replace the phrase "family and responsible persons" with the word "representatives." In addition, **Sections 87468(a)(1)(H) and (a)(1)(I)** are amended for clarity to replace "facility" with "licensee" because a licensee, not a facility, which is an inanimate object, can establish and provide information about policy.

The regulatory change to use the gender-neutral reference to "their" is necessary for clarity. The CDSS is applying personal rights equally to residents in RCFEs who may identify as male or female, as neither male or female, or as both male and female.

The CDSS is using its broad authority granted by Health and Safety Code section 1569.30 to require that residents' representatives be able to visit a facility, informed about care, and have communications answered for consistency with existing regulations. Section 87101 defines "representative" as "an individual who has authority to act on behalf of the resident; including but not limited to, a conservator, guardian, person authorized as agent in the resident's valid advance health care directive, the resident's spouse, registered domestic partner, or family member, a person designated by the resident, or other surrogate decisionmaker designated consistent with statutory and case law." People in these roles act on behalf of residents and may have a significant role in determining residents' care and services.

The regulatory change to refer to "licensee" is necessary for clarity. A licensee, not a facility, which is an inanimate object, can inform residents' representatives about care and services.

Amendment of **Section 87468(a)(1)(J)** is necessary to replace "facility's" with "licensee's" for clarity. A licensee, not a facility, which is an inanimate object, can establish and provide information about policy.

Delete Handbook Section 87468(a)(1)(J)

Specific Purpose/Factual Basis:

This handbook section is removed post-hearing since the handbooked Health and Safety Code section 1569.313 is referenced in Section 87468(a)(1)(J). Licensees can find the full text of this statute online at <u>California Legislative Information</u> (http://leginfo.legislature.ca.gov/faces/codes.xhtml).

Sections 87468(a)(1)(K) through (a)(1)(R) are Renumbered from Sections 87468(a)(11) through (a)(18)

Specific Purpose/Factual Basis:

Sections 87468(a)(11) through (a)(18) are renumbered to Sections 87468(a)(1)(K) through (a)(1)(R) to accommodate the adoption of Section 87468(a)(1) above.

Amendment of Sections 87468(a)(1)(K) and (a)(1)(L) are necessary to replace the phrase "his or her" in existing regulatory language with the word "their" for clarity. The CDSS is using the gender-neutral reference to "their" to apply personal rights equally to residents in RCFEs who may identify as male or female, as neither male or female, or as both male and female. There is a grammatical change to add a comma between "representatives" and "permitted" in Section 87468(a)(1)(K).

Amendment of **Section 87468(a)(1)(N)** is necessary to move the sentence "The licensee may require reimbursement for long distance calls" to adopt **Subsection (a)(1)(N)(1.)** of this section. This regulatory change is necessary for clarity. It separates the condition of permitting a licensee to require reimbursement for long distance calls that applies to the personal right from the personal right. The personal right is permitted to stand alone and be followed by the condition that applies.

There is a grammatical change to remove the comma between "medical care" and "or other services" in **Section 87468(a)(1)(P)**.

Section 87468(a)(2)

Specific Purpose:

This section is adopted to clarify that residents in privately operated RCFEs are afforded personal rights in statute, is amended post-hearing to 1) remove the word "only" and 2) replace the word "additional" with the word "also."

Factual Basis:

This regulatory change is necessary to clarify that residents in privately operated RCFEs are to be afforded personal rights in Health and Safety Code section 1569.269. Adoption of this regulation is necessary to comply with Health and Safety Code section 1569.269, added by AB 2171 (Chapter 702, Statutes of 2014). This statute establishes 30 personal rights for residents in RCFEs, some of which are not addressed by existing regulations, and applies these rights to residents in privately operated RCFEs. These personal rights are being incorporated by reference in these regulations.

Amendment of this section post-hearing is necessary for clarity. Use of the word "only" may cause this regulation to appear as though it conflicts with the regulation in Section 87468 (a)(1) by specifying that residents in privately operated facilities only have the rights

in Health and Safety Code section 1569.269. Use the word "also" is a clearer way of stating that residents of privately operated RCFEs have the rights in (a)(1) and this section.

Delete Proposed Handbook Section 87468(a)(2)

Specific Purpose/Factual Basis:

This handbook section is removed post-hearing since the handbooked Health and Safety Code section 1569.269 is referenced in Section 87468(a). Licensees can find the full text of this statute online at <u>California Legislative Information</u> (http://leginfo.legislature.ca.gov/faces/codes.xhtml).

Section 87468(b)

Specific Purpose:

This section is being amended to replace the phrase "responsible person or conservator" with the word "representative."

Factual Basis:

The CDSS is using its broad authority granted by Health and Safety Code section 1569.30 to require that residents' representatives be advised of, be given, and sign personal rights along with residents. Section 87101 defines "representative" as "an individual who has authority to act on behalf of the resident; including but not limited to, a conservator, guardian, person authorized as agent in the resident's valid advance health care directive, the resident's spouse, registered domestic partner, or family member, a person designated by the resident, or other surrogate decisionmaker designated consistent with statutory and case law." People in these roles act on behalf of residents and may have a significant role in determining residents' care and services.

Sections 87468(c) through (c)(2) Renumbered from Sections 87468(c) through (c)(3)

Specific Purpose:

These sections are amended to *remove* regulation in the existing Sections 87468(c) and (c)(1) through (c)(2) that requires facilities "licensed for seven (7) or more" to post complaint information and personal rights "or, in lieu of a posted copy of personal rights, instructions on how to obtain additional copies of these rights."

They are also amended to *add* regulations in new Section 87468(c) to require licensees of all RCFEs to post "personal rights and complaint information" in areas accessible to "residents' representatives, and the public" as well as residents and to *add* regulations in Sections 87468(c)(1) through (c)(3) to require accessible, consistent, and universal posting of resident personal rights and complaint information in all RCFEs..

Factual Basis:

Amendment of the regulation to remove reference to facilities licensed for seven (7) or more residents is necessary to clarify that, regardless of the number of residents in a facility and whether a facility is privately operated or publicly operated, personal rights and complaint information must be posted in all RCFEs.

(c) To comply with statute, the requirement that licensees post personal rights based on the number of residents in a facility will no longer apply to privately operated RCFEs. Health and Safety Code sections 1569.267(a) and (b), added to statute by AB 2171 (Chapter 702, Statutes of 2014) requires licensees of privately operated RCFEs, regardless of the number of residents in their facilities, to post information about resident personal rights. Given the requirement that licensees of privately operated RCFEs post personal rights, CDSS is using its broad authority to promulgate regulations for licensed RCFEs in Health and Safety Code section 1569.30 to also require that licensees of publicly operated RCFEs post personal rights. It also is necessary to remove existing regulation permitting licensees to either post personal rights or instructions on how to obtain additional copies of these rights in lieu of a posted copy for consistency with these requirements.

The CDSS is using its broad authority granted by Health and Safety Code section 1569.30 to require that personal rights and complaint information also be accessible to residents, their representatives, and the public for consistency with existing regulations. Section 87101 defines "representative" as "an individual who has authority to act on behalf of the resident; including but not limited to, a conservator, guardian, person authorized as agent in the resident's valid advance health care directive, the resident's spouse, registered domestic partner, or family member, a person designated by the resident, or other surrogate decisionmaker designated consistent with statutory and case law." People in these roles act on behalf of residents and need transparent access to personal rights and complaint information to support residents in regard to these rights when necessary. The public needs transparent access to personal rights and complaint information as they research RCFEs for friends or family or support friends or family in RCFEs.

- (c)(1) The requirement that licensees post procedures for filing confidential complaints is being superseded as necessary to comply with Health and Safety Code section 1569.33, amended in statute by SB 895 (Chapter 704, Statutes of 2014). This statute required CDSS to design a poster or cause a poster to be designed that contains information on how to report complaints. The CDSS has made the poster available and requires that it, or a poster that is consistent with the content of the poster provided by CDSS, be posted in all RCFEs.
- (c)(1)(A) The CDSS is using its broad authority granted by Health and Safety Code section 1569.30 to require that personal rights and complaint information also be accessible to residents' responsible persons or conservators and the public for consistency with existing regulations. Section 87101 defines "responsible person"

as an "...individual or individuals, including a relative, health care surrogate decision maker, or placement agency, who assist the resident in placement or assume varying degrees of responsibility for the resident's well-being" and "conservator" as "...a person appointed by the Superior Court pursuant to Probate Code section 1800 et. seq. or Welfare and Institutions Code section 5350, to care for the person, or estate, or person and estate, of an adult." People in these roles act on behalf of residents and need transparent access to personal rights and complaint information to support residents in regard to these rights when necessary. The public needs transparent access to personal rights and complaint information as they research RCFEs for friends or family or support friends or family in RCFEs.

- (c)(1)(B) The requirement that licensees of all RCFEs post resident personal rights as specified in Sections 87468(a)(1)(A) through (a)(1)(R), which are based on existing regulations, is necessary for consistency. The requirement that licensees of privately operated RCFEs post resident personal rights as specified in regulations is necessary to comply with Health and Safety Code section 1569.267(a), added to statute by AB 2171 (Chapter 702, Statutes of 2014), which requires these licensees to inform residents of personal rights in the California Code of Regulations (CCR), Title 22, Division 6, RCFE section 87468, Personal Rights as well as new statutory personal rights. The CDSS is using its broad authority granted by Health and Safety Code section 1569.30 to continue requiring that licensees of publicly operated RCFEs post resident personal rights as specified in regulations in this Phase I regulations package. These regulations will be followed by more extensive changes to resident personal rights for both privately operated and publicly operated facilities in a forthcoming "Phase II" regulations package.
- (c)(2) The requirement that licensees of privately operated RCFEs also post resident personal rights as specified in Health and Safety Code section 1569.269, which lists new statutory personal rights, is necessary to comply with statute. Health and Safety Code section 1569.265(b), added to statute by AB 2171 (Chapter 702, Statutes of 2014) specifies that personal rights in statute apply only to privately operated RCFEs. Health and Safety Code section 1569.267(a), also added to statute by AB 2171, requires licensees of privately operated RCFEs to inform residents of new statutory personal rights as well as personal rights in the CCR, Title 22, Division 6, RCFE section 87468, Personal Rights.
- (c)(2)(A) The requirement that licensees of all RCFEs post information on the appropriate reporting agency in case of a complaint or emergency by using a complaint information poster is necessary to comply with statute. A complaint poster is being made available to licensees by CDSS and must be posted in the main entryway of a facility to comply with Health and Safety Code section 1569.33, amended in statute by SB 895 (Chapter 704, Statutes of 2014). The Licensing Complaint Poster (PUB 475, 1/15) is incorporated in its entirety, by reference, in the proposed regulations. Although it is unduly cumbersome, expensive, and

otherwise impractical to publish this poster in the California Code of Regulations, it can be found on CDSS Community Care Licensing Division website at www.ccld.ca.gov. The CDSS is using its broad authority granted by Health and Safety Code section 1569.30 to permit licensees to develop their own complaint poster that is consistent with information on the complaint poster being made available by CDSS. This requirement is also necessary for clarity and consistency, to require that all RCFEs, regardless of whether they are privately operated or publicly operated, have universal posting of complaint information.

(c)(3) The requirement that licensees of all RCFEs post resident personal rights and complaint information in English and other languages as specified is necessary for clarity and consistency. Health and Safety Code section 1569.267(c), added to statute by AB 2171 (Chapter 702, Statutes of 2014) requires licensees of privately operated RCFEs to post personal rights both in English and in any other language in facilities where five percent or more of residents can only read in that language. The CDSS is using its broad authority to promulgate regulations for licensed RCFEs granted by Health and Safety Code section 1569.30 to extend these requirements to posting both personal rights and complaint information in English and other languages in all RCFEs. These extended requirements are necessary to provide licensees with a clear, measurable and consistent standard for posting this essential information in languages that can be read by residents. They are also necessary to ensure that residents have equal access to and awareness of this essential information.

These regulations meet the "clarity," "consistency" and "reference" standards of the Administrative Procedures Act (APA), Section 11349 of the Government Code, subsections (c), (d) and (e). It also meets the requirements of style pursuant to Section 11343.1 of the Government Code, and the principles of "plain English" rule drafting.

Modification:

Following the public hearing, the CDSS is making the following changes:

(c) This section is being further amended to specifically include "residents, their representatives, and the public" by placing a comma after "residents" and replacing the group "relatives, responsible persons, or conservators," with the broader term "representatives."

The pre-hearing proposed Sections 87468(c)(1), (c)(1)(A) and (B) are deleted. The pre-hearing proposed Sections 87468(c)(2) and (c)(3) are renumbered to Sections 87468(c)(1) and (c)(2) post-hearing to accommodate deletion of the pre-hearing proposed Section 87468(c)(1). Amendment of these sections is necessary post-hearing to delete the proposed Section 87468(c)(1) and subsections (c)(1)(A) through (c)(1)(B) to make the requirement to post personal rights generic in Section 87468(c) for clarity. All licensees are required to post these rights. It is self-evident that licensees of all facilities will need to post

the rights specified in Section 87468(a)(1) and licensees of privately operated facilities will need to post the rights in both Sections 87468(a)(1) and (a)(2).

- (c)(1)The requirement that licensees of all RCFEs post information on the appropriate reporting agency in case of a complaint or emergency by using a complaint information poster, described in subsection (c)(1)(A), is necessary to comply with statute. A complaint poster is being made available to licensees by CDSS and must be posted in the main entryway of a facility to comply with Health and Safety Code section 1569.33, amended in statute by SB 895 (Chapter 704, Statutes of 2014). The Residential Care Facility for the Elderly (RCFE) Complaint Poster (PUB 475, 1/15) is incorporated in its entirety, by reference, in the proposed regulations. Although it is unduly cumbersome, expensive, and otherwise impractical to publish this poster in the California Code of Regulations, it can be found on CDSS Community Care Licensing Division website at www.ccld.ca.gov. The CDSS is using its broad authority granted by Health and Safety Code section 1569.30 to permit licensees to develop their own complaint poster that is consistent with information on the complaint poster being made available by CDSS. This requirement is also necessary for clarity and consistency, to require that all RCFEs, regardless of whether they are privately operated or publicly operated, have universal posting of complaint information.
- (c)(1)(A) This section was renumbered from pre-hearing proposed section (c)(2)(A) and the title to PUB 475 was corrected to Residential Care Facility for the Elderly (RCFE) Complaint Poster, removing the word "Licensing."
- The requirement that licensees of all RCFEs post resident personal rights (c)(2)and complaint information in English and other languages as specified is necessary for clarity and consistency. Health and Safety Code section 1569.267(c), added to statute by AB 2171 (Chapter 702, Statutes of 2014) requires licensees of privately operated RCFEs to post personal rights both in English and in any other language in facilities where five percent or more of residents can only read in that other language. The CDSS is using its broad authority to promulgate regulations for licensed RCFEs granted by Health and Safety Code section 1569.30 to extend these requirements to posting both personal rights and complaint information in English and other languages in all RCFEs. These extended requirements are necessary to provide licensees with a clear, measurable and consistent standard for posting this essential information in languages that can be read by residents. They are also necessary to ensure that residents who read in other languages have equal access to and awareness of personal rights and complaint information.

Section 87468(d)

Specific Purpose:

This section is amended to delete the existing regulation and adopt a new regulation. The regulation being repealed required that licensees post personal rights and complaint information "in English, and in facilities where a significant portion of the residents cannot read English, in the language they can read." The adopted regulation requires that licensees of all RCFEs include the language primarily read by each of their residents in a list of residents to be provided to CDSS upon request.

Factual Basis:

It is necessary to remove the existing requirement for posting personal rights and complaint information in other languages to clarify that the requirement that a "significant portion" of residents be unable to read English no longer applies to all RCFEs. The existing requirement is inconsistent with Health and Safety Code section 1569.267(c), added to statute by AB 2171 (Chapter 702, Statutes of 2014), which requires licensees of privately operated RCFEs to post personal rights both in English and in any other language in facilities where five percent or more of residents can only read in that language. Further, the term "significant" is subjective and does not provide necessary clarity in regard to the specific number of residents in a given facility that would need to be unable to read English for the requirement to apply.

The addition of regulation is necessary for consistency with existing requirements in the CCR, Title 22, Division 6, RCFE section 87508, Register of Residents. This section requires that licensees ensure that a current register of all residents in a RCFE is maintained and contains specified updated information. It also requires that registers of residents be treated as confidential and be made available to the licensing agency to inspect, audit and copy upon demand during normal business hours. The CDSS is using its broad authority to promulgate regulations granted by Health and Safety Code section 1569.30 to require that this list also include languages read by residents and apply to all RCFEs. This regulation will, when residents in RCFEs read in languages other than English, provide CDSS with a readily available means of identifying languages read by residents to determine whether licensees comply with posting requirements. It will also assist in mitigating the costs of resident records review that might otherwise be incurred to implement AB 2171.

Section 87612(a)(10)

Specific Purpose:

This section is amended to replace "pressure sores (dermal ulcers)" with "pressure injuries."

Factual Basis:

Amendment to this section, which addresses care for residents with restricted health conditions, is necessary to clarify that Stage 1 and 2 "pressure injuries" are considered restricted health conditions. This amendment is consistent with a NPUAP change in terminology from "pressure ulcer" to "pressure injury" announced in an April 13, 2016 NPUAP press release (http://www.npuap.org/national-pressure-ulcer-advisory-panel-npuap-announces-a-change-in-terminology-from-pressure-ulcer-to-pressure-injury-and-updates-the-stages-of-pressure-injury/).

This amendment is also consistent with the NPUAP definitions of Stage 1 and 2 pressure injuries. The NPUAP defines a Stage 1 pressure injury as having "intact skin with a localized area" of abnormality. A Stage 2 pressure injury is defined by the NPUAP as a "partial-thickness loss of skin with exposed dermis" in which the injury has a wound bed that may be pink or red in color and moist. The NPUAP further states that the injury may also look like "an intact or ruptured serum-filled blister." This amendment clarifies that less serious Stage 1 and 2 pressure injuries shall be cared for in an RCFE as specified for healing wounds in Section 87631.

Section 87615(a)(1)

Specific Purpose:

This section is amended to replace "pressure sores (dermal ulcers)" with "pressure injuries or deep tissue pressure injuries."

Factual Basis:

Amendment to this section, which addresses prohibited health conditions, is necessary to establish that Stage 3 and 4 "pressure injuries" or "deep tissue pressure injuries" are considered prohibited health conditions. This amendment is consistent with a NPUAP change in terminology from "pressure ulcer" to "pressure injury" and "deep tissue pressure injury" terminology addressed in an April 13, 2016 NPUAP press release (http://www.npuap.org/national-pressure-ulcer-advisory-panel-npuap-announces-a-change-in-terminology-from-pressure-ulcer-to-pressure-injury-and-updates-the-stages-of-pressure-injury/). This amendment is also consistent with the NPUAP definitions of Stage 3 and 4 pressure injuries and deep tissue pressure injuries.

The NPUAP defines a Stage 3 pressure injury as "...loss of skin, in which adipose (fat) is visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present." The NPUAP further states that "areas of significant adiposity can develop deep wounds." A Stage 4 pressure injury is defined by the NPUAP as "...skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer." The NPUAP further states that "Epibole (rolled edges), undermining and/or tunneling often occur." In the case of either type of pressure injury, the NPUAP states that depth of the injury varies by location on the body and the injury may have visible slough

and/or eschar. A Stage 3 or 4 deep tissue pressure injury is defined by the NPUAP as having visible "...necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle or other underlying structures..." Given that these pressure injuries and deep tissue pressure injuries are more serious, they cannot be cared for in a RCFE.

Section 87615(a)(2)

Specific Purpose:

This section is adopted to include the health condition of having "unstageable wounds" in the list of health conditions that are prohibited in all RCFEs.

Factual Basis:

Adoption of this regulation is necessary to clarify that licensees of all RCFEs may not admit or retain residents with unstageable wounds. An unstageable wound is defined by the NPUAP as a "full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed." Until enough slough and/or eschar can be removed to expose the base of the wound, the depth and stage of the wound cannot be determined. Adoption of this regulation is also necessary for consistency with existing regulations. Both Stage 3 and 4 pressure sores (dermal ulcers) are included in Section 87615(a)(1) as health conditions that are prohibited in all RCFEs. Unstageable wounds are considered by the NPUAP to be either Stage 3 or 4 ulcers that cannot definitively be placed in either of these stages due to eschar that obstructs clear observation of the wound. The CDSS is using its broad authority to promulgate regulations for licensed RCFEs in Health and Safety Code section 1569.30 to specify that unstageable wounds are also prohibited health conditions.

Modification:

Following the public hearing, the CDSS is making changes to this section and definitions in Section 87101 for clarity purposes.

The CDSS is replacing "wounds" with "pressure injuries or deep tissue pressure injuries," both of which may be unstageable. It is also adding definitions for "pressure injury," "unstageable pressure injury" and "deep tissue pressure injury" to define terms used by the medical profession that may be unfamiliar to licensees and clarify what constitutes these injuries.

Sections 87615(a)(3) through (a)(7) are Renumbered from Sections 87615(a)(2) through (a)(6)

Specific Purpose/Factual Basis:

Sections 87615(a)(2) through (a)(6) are renumbered to Sections 87615(a)(3) through (a)(7) to accommodate the adoption of Section 87615(a)(2).

Amendment of **Section 87615(a)(3)** is necessary to replace "care" with "tubes" for clarity. "Gastrostomy tubes" describes health conditions that residents may have that require specialized care. Use of the term "tubes" is also consistent with "naso-gastric tubes" in Section 87615(a)(4)

Amendment of **Section 87615(a)(5)** is necessary to spell out "staph" as "staphylococcus aureus" for clarity. The terms "staphylococcus aureus" or "staph" describe the same type of health conditions that residents may have that require specialized care. Either of these terms may be more familiar to licensees.

Sections 87631(a)(3) and (a)(3)(A)

Specific Purpose:

These sections are amended to replace "pressure sores (dermal ulcers)" with "pressure injuries." They are also being amended to clarify that a physician, as well as an appropriately skilled professional, may diagnose and treat a pressure injury.

Factual Basis:

Amendment of these regulations, which address care for residents with healing wounds, to replace the terms "pressure sores (dermal ulcers)" with "pressure injuries" is necessary to clarify that the term "pressure injuries" now applies to these types of wounds. This amendment is consistent with a NPUAP change in terminology from "pressure ulcer" to "pressure injury" announced in an April 13, 2016 NPUAP press release (http://www.npuap.org/national-pressure-ulcer-advisory-panel-npuap-announces-a-change-in-terminology-from-pressure-ulcer-to-pressure-injury-and-updates-the-stages-of-pressure-injury/).

- (a)(3) This amendment to require that Stage 1 or 2 pressure injuries be cared for in a RCFE under certain conditions is necessary for consistency with the NPUAP definition of Stage 1 and 2 pressure injuries in its press release announcing the change in terminology to "pressure injury." It is also consistent with the amendment to regulation in Section 87612 to require that a licensee provide care for residents with Stage 1 and 2 pressure injuries as specified in this section. Existing regulatory language, which permitted a pressure sore (dermal ulcer) and will now permit a pressure injury to be diagnosed by a physician or an appropriately skilled professional, remains consistent with scope of practice for a physician and the health care providers that are included in the definition for appropriately skilled professional in Section 87101. Including a physician as being able to diagnose a pressure injury is also consistent with existing language that refers to physician in the definition for "healing wounds" in Section 87101.
- (a)(3)(A) The amendment to require that a resident receive care for a pressure injury, as was required for a pressure sore (dermal ulcer), from a physician or an

appropriately skilled professional remains consistent with scope of practice for a physician or the health care providers that are included in the definition for appropriately skilled professional in Section 87101.

b) <u>Identification of Documents Upon Which Department Is Relying</u>

Documents relied upon in proposing these regulations are:

AB 2171 (Chapter 702, Statutes of 2014);

AB 878 (Chapter 526, Statutes of 1993);

SB 895 (Chapter 704, Statutes of 2014);

SB 211 (Chapter 409, Statutes of 2003); and

California Department of Public Health All Facility Letter (AFL) 08-09 on Mandated Reporting of Staging of Pressure Ulcers, dated May 27, 2008;

National Pressure Ulcer Advisory Panel (NPUAP) Press Release on change in terminology from pressure ulcer to pressure injury and updates the stages of pressure injury, dated April 13, 2016;

National Pressure Ulcer Advisory Panel (NPUAP), European Pressure Ulcer Advisory Panel (EPUAP) and Japanese Society of Pressure Ulcers (JSPU), et al., as sponsored by Gaymar Industries, Inc. (now Stryker) on Shear: A contributory factor in pressure ulceration slide set on NPUAP website September 21, 2016; and

WoundSource article on Identifying Types of Tissues Found in Pressure Ulcers, dated November 20, 2014.

c) Local Mandate Statement

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

AB 2171 expands the scope of a crime. SB 211 creates a new crime. Both impose a statemandated local program. However, neither of these laws require reimbursement pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

d) Statement of Alternatives Considered

In developing the regulatory action, CDSS did not consider any other alternatives than the one proposed because this was the most effective. No reasonable alternative has been presented for review.

The CDSS must determine that no reasonable alternative considered or that has otherwise been identified and brought to the attention of CDSS would be more effective in carrying out the purpose for which the regulations are proposed or would be as effective as and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

e) Statement of Significant Adverse Economic Impact On Business

The CDSS has made an initial determination that the proposed action will not have a significant, statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. Expanded personal rights regulations to implement AB 2171 would apply to privately operated RCFEs. Existing regulatory personal rights would continue to apply to both privately and publicly operated RCFEs. A modified regulation affording residents the personal right to make complaints to specified agencies would apply to all RCFEs, regardless of whether they are privately operated or publicly operated. Regardless of number of residents, all licensees would be required to post personal rights and complaint information, and post this information in other languages when five percent or more of residents primarily read in another language.

There will be some administrative costs to licensees of all RCFEs as a result of statutory requirements enacted by AB 2171, SB 211 and SB 895. Licensees would need to update admission agreements as they relate to resident personal rights and facility procedures as they relate to posting these rights and complaint information in other languages read by five percent or more of residents in a facility. Licensees would also need to develop and

implement a method for collecting information from residents on the language they primarily read and compile this information into a single list that is kept accurate and current. The CDSS anticipates that this list will result in negligible cost to licensees since existing regulations in the CCR, Title 22, section 87508 currently require a register of residents, which would be expanded to address languages read by residents. In addition, licensees would need to update the posted resident personal rights and/or complaint information whenever the composition of languages primarily read by residents' changes.

Miscellaneous changes to regulations that do not address resident personal rights will require licensees of RCFEs to not accept or retain residents with unstageable wounds. However, this and other miscellaneous changes do not have any statewide adverse economic impact directly affecting businesses in California.

f) Economic Impact Assessment

In accordance with Government Code section 11346.3(b), CDSS has made economic impact assessments regarding the proposed regulations to implement: AB 2171 (Chapter 702, Statutes of 2014); AB 878 (Chapter 526, Statutes of 1993); SB 895 (Chapter 704, Statutes of 2014); and SB 211 (Chapter 409, Statutes of 2003). The CDSS has made an initial determination that the proposed regulations will not have a significant, statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states, as identified by the following:

Creation or Elimination of Jobs Within the State of California

As a result of the passage of AB 2171 and SB 211, these amendments modify some of, and add to, the resident personal rights that have been in the CCR, Title 22, Division 6, RCFE, section 87468, since 2008. As a result of the passage of SB 895, these amendments require that licensees post a poster on how to file complaints, modifying the requirement to post procedures for filing complaints that has been in the CCR, Title 22, Division 6, RCFE, section 87468, since 2008. Other amendments to regulations that do not address personal rights, but are the result of miscellaneous changes in law or standards of care either modify, or are consistent with, requirements that have been in the CCR, Title 22, Division 6, RCFE, since 2008.

The proposed amendments to regulations in this regulations package will neither create nor eliminate jobs in the State of California. They amend existing regulatory requirements as a result of changes in statutory requirements enacted by the bills specified above. The amendments to regulations are consistent with requirements that have been in existing regulations for a number of years. For this reason, CDSS has determined that the proposed regulations will not have an impact on the creation or elimination of jobs in the State of California.

Creation of New or Elimination of Existing Businesses Within the State of California

As a result of the passage of AB 2171 and SB 211, these amendments modify some of, and add to, the resident personal rights that have been in the CCR, Title 22, Division 6, RCFE, section 87468, since 2008. As a result of the passage of SB 895, these amendments require that licensees post a poster on how to file complaints, modifying the requirement to post procedures for filing complaints that has been in the CCR, Title 22, Division 6, RCFE, section 87468, since 2008. Other amendments to regulations that do not address personal rights, but are the result of miscellaneous changes in law or standards of care either modify, or are consistent with, requirements that have been in the CCR, Title 22, Division 6, RCFE, since 2008.

The proposed amendments to regulations in this regulations package will neither create nor eliminate existing businesses in the State of California. They amend existing regulatory requirements as a result of changes in statutory requirements enacted by the bills specified above. The amendments to regulations are consistent with requirements that have been in existing regulations for a number of years. For this reason, CDSS has determined that the proposed regulations will not have an impact on the expansion or elimination of existing businesses in the State of California.

Expansion or Elimination of Businesses Currently Doing Business Within the State of California

As a result of the passage of AB 2171 and SB 211, these amendments modify some of, and add to, the resident personal rights that have been in the CCR, Title 22, Division 6, RCFE, section 87468, since 2008. As a result of the passage of SB 895, these amendments require that licensees post a poster on how to file complaints, modifying the requirement to post procedures for filing complaints that has been in the CCR, Title 22, Division 6, RCFE, section 87468, since 2008. Other amendments to regulations that do not address personal rights, but are the result of miscellaneous changes in law or standards of care either modify, or are consistent with, requirements that have been in the CCR, Title 22, Division 6, RCFE, since 2008.

The proposed amendments to regulations in this regulations package will neither expand nor eliminate businesses currently doing business in the State of California. They amend existing regulatory requirements as a result of changes in statutory requirements enacted by the bills specified above. The amendments to regulations are consistent with requirements that have been in existing regulations for a number of years. For this reason, CDSS has determined that the proposed regulations will not have an impact on the expansion or elimination of businesses currently doing business in the State of California.

Benefits of the Regulations

The CDSS anticipates that the proposed regulations will benefit the health and welfare of residents receiving care in privately operated RCFEs by ensuring that they have statutory personal rights that are to be observed by licensees. These personal rights are in the spirit of

the Resident Bill of Rights implemented by the California Advocates for Nursing Home Reform, California Department of Public Health, and Medicare. These regulations will allow residents to have additional personal rights in statute that are more responsive to their individual desires and needs, such as the right to: receive a comprehensive description of how residents' needs are evaluated; share a room with any other resident of their choice when there is mutual consent; and prompt access to all of their records. Residents in both privately operated and publicly operated RCFEs will continue to have the protection of personal rights, which includes a clarification and strengthening of a personal right, in existing regulations. The personal rights being implemented in these regulations provide essential protection for residents of all RCFEs who are often vulnerable elderly and without advocates or family to ensure that their rights are observed. They are intended to prevent discrimination and promote fairness and equity. The proposed regulations will also ensure that residents, including those who read primarily in other languages, in all RCFEs have equal access to and awareness of personal rights and complaint information so that they can advocate for themselves when necessary. In addition, the proposed regulations will benefit licensee compliance in providing care to residents. There are no additional benefits for worker safety or the state's environment, as the regulations only affect residents in California RCFEs.

Documents Relied Upon

Documents relied upon in proposing these regulations are:

AB 2171 (Chapter 702, Statutes of 2014); AB 878 (Chapter 526, Statutes of 1993); SB 895 (Chapter 704, Statutes of 2014); and SB 211 (Chapter 409, Statutes of 2003); and California Department of Public Health AFL 08-09 on Mandated Reporting of Staging of Pressure Ulcers, dated May 27, 2008; National Pressure Ulcer Advisory Panel (NPUAP) Press Release on change in terminology from pressure ulcer to pressure injury and updates the stages of pressure injury, dated April 13, 2016; National Pressure Ulcer Advisory Panel (NPUAP), European Pressure Ulcer Advisory Panel (EPUAP) and Japanese Society of Pressure Ulcers (JSPU), et al., as sponsored by Gaymar Industries, Inc. (now Stryker) on Shear: A contributory factor in pressure ulceration slide set on NPUAP website September 21, 2016; and WoundSource article on Identifying Types of Tissues Found in Pressure Ulcers, dated November 20, 2014.

g) Benefits Anticipated from Regulatory Action

The CDSS anticipates that the proposed regulations will benefit the health and welfare of residents receiving care in privately operated RCFEs by ensuring that they have statutory personal rights that are to be observed by licensees. These personal rights are in the spirit of the Resident Bill of Rights implemented by the California Advocates for Nursing Home Reform, California Department of Public Health, and Medicare. These regulations will allow residents to have additional personal rights in statute that are more responsive to their individual desires and needs, such as the right to: receive a comprehensive description of how residents' needs are evaluated; share a room with any other resident of their choice when there is mutual consent; and prompt access to all of their records. Residents in both

privately operated and publicly operated RCFEs will continue to have the protection of personal rights, which includes a clarification and strengthening of a personal right, in existing regulations. The personal rights being implemented in these regulations provide essential protection for residents of all RCFEs who are often vulnerable elderly and without advocates or family to ensure that their rights are observed. These personal rights are intended to prevent discrimination and promote fairness and equity. The proposed regulations will also ensure that residents, including those who read primarily in other languages, in all RCFEs have equal access to and awareness of personal rights and complaint information so that they can advocate for themselves when necessary. In addition, the proposed regulations will benefit licensee compliance in providing care to residents. These proposed regulations have no direct benefit to worker safety or the state's environment, as the proposed regulations only affect residents in RCFEs.

h) Statement of Specific Technology or Equipment

This regulatory action will not mandate the use of new, specific technologies or equipment.

i) Testimony and Response (June 10, 2016, through July 27, 2016)

The CDSS noticed these regulations to the public for a 45-day comment period in the Office of Administrative Law California Regulatory Notice Register, Register 2016, No. 24-Z, dated June 10, 2016. These regulations were considered as Item #1 at a public hearing held on July 27, 2016, in Sacramento, California. The public comment period closed at 5:00 p.m. on July 27, 2016.

The following written testimony was received during the 45-day comment period:

Jody L. Spiegel, Staff Attorney and Patricia L. McGinnis, Executive Director, California Advocates for Nursing Home Reform (CANHR)

1. Section 87109(b)

Comment:

CANHR recommends that the subsection be amended as follows:

(b) The licensee shall notify the licensing agency, the long-term care ombudsman and all residents receiving services, or their responsible persons, in writing as soon as possible and in all cases at least thirty (30) days prior to the effective date that any change in ownership of the facility occurs as required by Health and Safety Code section 1569.191(a)(1) of any sale or transfer of the property or business, and in all cases at least 30 days prior to the transfer of the property or business, or at the time that a bona fide offer is made, whichever period is longer.

CANHR's proposed amendment above tracks the language of Health & Safety Code section 1569.191(a)(1) verbatim with respect to the notification time period. Neither the current regulation, nor the proposed regulation, accurately describe the statutory notification time period, insofar as they both fail to reference the potentially longer time period required by Health & Safety Code section 1569.191(a)(1) if a bona fide offer is made more than 30 days prior to the transfer of the property or business. The above amendment is necessary to accomplish the Department's stated purpose of clarifying the timeframe for licensees to provide notification. The proposed amendment also clarifies the circumstances under which notice shall be given, i.e., the sale or transfer of the property or business, to conform with the language in Health & Safety Code section 1569.191(a). Finally, the proposed amendment adds the long-term care ombudsman to the list of persons required to receive notification. CANHR recommends that the Department require the licensee to also notify the long-term care ombudsman so that the ombudsman can assist residents with issues related to the sale or transfer of the property or business.

Response:

The Department appreciates this comment. We agree that clarification of the requirements of Health and Safety Code section 1569.191 is needed. The original intent of the proposed regulation was to clarify that the timeframe for licensees to provide notification of change in ownership must be "...at least 30 days prior.." as required by Health and Safety Code section 1569.191(a)(1) rather than the 60 days as required by current regulations. The Department acknowledges the specified timeframe applies to any of the events, i.e., sale or transfer of the property or business or a bona fide offer is made that is expected to result in the pending sale or transfer of a facility, as specified in the statute. The Department is amending Section 87109(b) to read:

(b) The licensee shall notify the licensing agency and all residents receiving services, or their responsible persons, in writing as soon as possible and in all cases at least sixty (60) thirty (30) days prior to the effective date that any change in ownership of the facility occurs as required by any of the events specified in Health and Safety Code section 1569.191(a)(1).

The Department will not be adding the long-term care ombudsman to the persons that a licensee must notify, as this is not required by Health and Safety Code section 1569.191(a)(1). A licensee must notify the long-term care ombudsman when emergency events, i.e., a notice of default, notice of trustee's sale, or any other indication of foreclosure is issued on the property, occurs as specified in Health and Safety Code section 1569.686(a).

2. <u>Section 87468(a)(1)(D)</u>

Comment:

CANHR recommends that the original language in the subsection be retained to read as follows:

(D) To be informed by the licensee of the provisions of law regarding complaints and of procedures to confidentially register complaints, including, but not limited to, the address and telephone number of the complaint receiving unit of the licensing agency, and how to confidentially contact the Community Care Licensing Division of the California Department of Social Services, the long-term care ombudsman, or both, regarding grievances against the facility.

CANHR's proposed amendment retains the language currently in the regulation to ensure that residents are informed not only of their right to file grievances, but also how to do so. The right to file a grievance is meaningless unless residents are provided with information on how to exercise that right.

Response:

The Department appreciates this comment. We agree to retain the original language in this section for clarity in regard to exercising the right to file grievances. However, we are also including a reference to Health and Safety Code section 1569.885, which was added to statute by SB 211 (Chapter 409, Statutes of 2003). This statute requires that residents be informed of their right to contact the CDSS, the long-term care ombudsman, or both, to make complaints in regard to a licensed facility.

A licensee is required to let residents know how they may file complaints by posting the Residential Care Facility for the Elderly Complaint Poster (PUB 475), required by SB 895 (Chapter 704, Statutes of 2014). This poster includes contact information for reporting complaints to the CDSS.

A licensee is also required to inform residents of their personal rights, which include the right to contact the CDSS and/or the long-term care ombudsman regarding a grievance about the licensee, by providing them with a copy of the rights and posting the rights in a facility. In informing residents of their personal rights, a licensee has the option to use the appropriate RCFE personal rights form (LIC 613C or LIC 613C-2), which can be found on the CDSS CCLD website at On-line Forms and Publications I - L (http://www.dss.cahwnet.gov/cdssweb/PG166.htm#lic).

The contact information for the CDSS, the State Ombudsman and the local Ombudsman is provided on these RCFE personal rights forms.

3. <u>Section 87468(a)(2)</u>

Comment:

CANHR recommends that the Department strike the language "in privately operated facilities." The Department is charged with protecting the health and safety of <u>all</u> RCFE residents, and not just residents in privately operated facilities. Residents in publicly operated RCFEs should not have fewer rights or protections than residents in privately

operated facilities. The Department should use its broad authority under Health & Safety Code section 1569.30 to extend the additional rights to residents of all RCFEs, as it is proposing to do in connection with the posting of these very same rights under Section 87468(c). See Initial Statement of Reasons, Sections 87468(c) through (c)(3), Factual Basis at page 8.

CANHR further recommends that the Department list the rights specified in section 1569.269 in the regulation itself, instead of requiring licensing staff, licensees, consumers and advocates to go to another location to determine the personal rights to which residents are entitled. The Department says that its purpose is to "expand the personal rights afforded to residents in RCFEs in this 'Phase 1' regulations package." If the Department wishes to accomplish its stated purpose, it should list the additional rights to which RCFE residents are **now** entitled in the regulation. The Department does not need to wait until it completes its Phase 2 regulation package to include the rights which are currently set forth in section 1569.269, and can utilize the Phase 2 package to further clarify the rights, if necessary.

Response:

The Department appreciates this comment. However, we are maintaining the proposed language. The Department does not have the authority to extend the personal rights in this regulations package since Health and Safety Code section 1569.265(b), added to statute by AB 2171 (Chapter 702, Statutes of 2014), only gives these rights to residents of privately operated facilities. The Department is incorporating the personal rights to which residents in privately operated RCFEs are now entitled by reference to Health and Safety Code section 1569.269, rather than listing them, in regulation. We no longer plan to complete a Phase 2 regulations package since we have determined that it is not necessary to further clarify the rights.

4. <u>Section 87468(c)(2)(A)</u>

Comment:

Licensees are required to post information on filing confidential complaints. The referenced Licensing Complaint Poster (PUB 475) does not state that residents may file confidential complaints. CANHR recommends that the poster be revised to state that complaints may be filed confidentially so that licensees are not required to post additional information on the procedure for filing confidential complaints.

Response:

The Department appreciates this comment on this section, which is renumbered to Section 87468(c)(1)(A) from 87468(c)(2)(A) post-hearing. However, we are maintaining the language currently in the Residential Care Facility for the Elderly (RCFE) Complaint Poster (PUB 475). The requirement that licensees post additional information on the procedure for filing confidential complaints is met by the requirement that they post personal rights and the complaint poster as specified in Section 87468(c). The personal rights forms (LIC 613C

or LIC 613C-2) that a licensee has the option to use and the complaint poster (PUB 475) provide necessary information on the procedures for filing complaints. A statement that complaints may be filed confidentially is not required for the poster by SB 895 (Chapter 704, Statutes of 2014).

The CDSS has procedures in place to assure and safeguard confidentiality of residents and complainants, including residents, who are involved in a complaint and complaints in regard to a RCFE. CDSS staff are required to assure complainants of confidentiality (Reference Material, Section 3-2011). Staff are required to treat complaints as confidential documents [Reference Material, Section 1-1130(5.)]. They are also required to follow requirements for confidentiality as required by the Information Practices Act of 1977 and the California Public Records Act (Reference Material, Section 2-6000). Department policies and procedures require staff to use specified forms, such as the Confidential Names form (LIC 811), to safeguard confidentiality (Reference Material, Section 1-0780(3.) and Section 3-3300). These procedures can be found on the CDSS CCLD website at Reference Material (http://ccld.ca.gov/PG545.htm).

5. Section 87615(a)(2)

Comment:

CANHR recommends that the proposed addition of "Unstageable wounds" as a prohibited health condition be deleted. The term "Unstageable wounds" is not universally understood. The stated definition by the National Pressure Ulcer Advisory Panel (NPUAP) is vague and confusing. If the Department wishes to include "Stage 3 or 4 ulcers that cannot be definitely placed in either of these categories" as a prohibited health condition, it can broaden the definition of Stage 3 and 4 pressure sores, rather than using an ambiguous term.

Response:

The Department appreciates this comment. We agree that some clarification of the term "unstageable wounds" is needed. The Department is amending definitions in regulations to add a definition for "unstageable pressure injury" and is amending the proposed language in this section from "unstageable wounds" to "unstageable pressure injuries." The Department is also amending definitions in regulations to add a definition for "pressure injury" and "deep tissue pressure injury." These changes are consistent with the current terminology for "unstageable wound" based on an April 13, 2016 NPUAP press release (http://www.npuap.org/national-pressure-ulcer-advisory-panel-npuap-announces-a-change-in-terminology-from-pressure-ulcer-to-pressure-injury-and-updates-the-ages-of-pressure-injury/).

The language in the definition for "unstageable pressure injury" clarifies that such a pressure injury is considered unstageable due to the inability of being able to see all of the wound until it has been cleaned. It also clarifies what an unstageable pressure injury will look like upon observation. The Department recognizes that a licensee is typically not a medical professional who is qualified to "stage" a pressure injury and does not permit a licensee to

make a diagnosis of an unstageable pressure injury. For these reasons, the definition includes the injury being unstageable as identified by an appropriately skilled professional. The definition of "unstageable pressure injury" is being added in California Code of Regulations (CCR), Title 22, Section 87101 to read:

- (u) (1) (2) (Continued)
 - (3) "Unstageable pressure injury" means a pressure injury with obscured full-thickness loss of skin and tissue in which the extent of tissue damage in the ulcer cannot be confirmed because it is covered by abnormal tissue in the form of slough or eschar. If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed.

The language in the definition for "pressure injury" clarifies that this type of injury is caused by damage to the skin and/or soft tissue under the skin that is the result of pressure on a part of the body. It also clarifies what a pressure injury will look like upon observation. The Department recognizes that a licensee is typically not a medical professional who is qualified to "stage" a pressure injury and does not permit a licensee to make a diagnosis of a pressure injury. For this reason, the definition includes the injury being staged as identified by an appropriately skilled professional. The definition of "pressure injury" is being added, and Sections 87101(p)(4) through (p)(6) are renumbered from Sections 87101(p)(3) through (p)(5) to accommodate the addition of this definition, in California Code of Regulations (CCR), Title 22, Section 87101 to read:

- (p) (1) (2) (Continued)
 - (3) "Pressure Injury" means localized damage to the skin and/or soft tissue under the skin that is usually over a bony part of the body or related to a medical or other device. This damage can appear as intact skin or an open ulcer and may be painful. It occurs as a result of intense and/or prolonged pressure on the affected part of the body or pressure combined with shear, an action or stress that causes internal parts of the body to become deformed. Based on appearance and severity, the damage to tissue is a Stage 1, 2, 3, or 4 pressure injury.
 - (34) (Continued)
 - (45) (Continued)
 - $(\underline{56})$ (Continued)

The language in the definition for "deep tissue pressure injury" clarifies that such a pressure injury is considered to be a deep tissue injury due to persistent discoloration of skin or a separation in skin that reveals tissue and other structures underneath. It also clarifies what a deep tissue pressure injury will look like upon observation. The Department recognizes that a licensee is typically not a medical professional who is qualified to "stage" a deep tissue

pressure injury and does not permit a licensee to make a diagnosis of a deep tissue pressure injury. For these reasons, the definition includes the injury as being a deep tissue pressure injury as identified by a physician or an appropriately skilled professional. The definition of "deep tissue pressure injury" is being added, and Sections 87101(d)(3) through (d)(11) are renumbered from Sections 87101(d)(2) through (d)(10) to accommodate the addition of this definition, in California Code of Regulations (CCR), Title 22, Section 87101 to read:

- (d) (1) (Continued)
 - Deep Tissue Pressure Injury means intact or non-intact skin with a localized area of persistent deep red, maroon, or purple discoloration or a separation in the protective outer layer of the skin that reveals a dark wound bed or blood-filled blister. Discoloration of the injury may appear differently in darkly pigmented skin. This injury occurs as a result of intense and/or prolonged pressure and the force of shear, an action or stress that causes internal parts of the body to become deformed, at the bone-to-muscle interface. If tissue, fascia, muscle, or other structures under the skin are visible, there will be a full thickness pressure injury that is identified as unstageable, a Stage 3, or Stage 4 deep tissue injury.
 - $(\underline{23})$ (Continued)
 - (34) (Continued)
 - (45) (Continued)
 - $(\underline{56})$ (Continued)
 - (67) (Continued)
 - (78) (Continued)
 - (89) (Continued)
 - (910) (Continued)
 - (1011) (Continued)